



William C. Baton  
Phone: (973) 286-6722  
Fax: (973) 286-6822  
wbaton@saul.com  
www.saul.com

August 11, 2020

**VIA ECF**

The Honorable Kevin McNulty, U.S.D.J.  
United States District Court for the District of New Jersey  
Frank R. Lautenberg U.S. Post Office & Courthouse  
1 Federal Square  
Newark, New Jersey 07101

Re: *Indivior Inc., et al. v. Dr. Reddy's Laboratories S.A., et al.*  
Civil Action No. 17-7111 (KM)(CLW)

Dear Judge McNulty:

This firm, together with Covington & Burling LLP and Steptoe & Johnson LLP, represents plaintiffs Indivior Inc., Indivior UK Limited (collectively, "Indivior"), and Aquestive Therapeutics, Inc. ("Aquestive") (together with Indivior, "Plaintiffs") in the above-captioned matter. We write in reply to Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc.'s (collectively, "DRL") opposition to Plaintiffs' request for leave to file an early summary judgment motion on DRL's antitrust counterclaims. *See* D.I. 408, 410. In their opening letter, Plaintiffs established that:

- Objective baselessness is a question of law amenable to resolution now because there are no predicate facts from the preliminary injunction proceeding in dispute that necessitate discovery. *Id.* at 2-4.
- Plaintiffs' position on the key claim construction issue for the '305 patent was not objectively baseless. *Id.* at 3.
- The key findings that led Your Honor to issue the preliminary injunction—*i.e.*, that Plaintiffs had a likelihood of success on the merits and the public interest favored the protection of Plaintiffs' patent rights—would not change even if the allegations in the criminal indictment against Indivior are assumed true for purposes of Plaintiffs' contemplated motion. *Id.* at 5.
- The Court was well aware at the time it issued the injunction that Indivior had been accused by the government and private plaintiffs of an allegedly anticompetitive effort to increase Suboxone® Film sales. *Id.*

Hon. Kevin McNulty, U.S.D.J.  
August 11, 2020  
Page 2

In its response, DRL does *not* take issue with any of this. DRL does not point to a single disputed material predicate fact about the preliminary injunction motion proceedings, essentially concedes that Plaintiffs' claim construction position was colorable, and does not identify any material information unknown to Your Honor during the preliminary injunction proceedings that might have resulted in denial of Plaintiffs' preliminary injunction motion. Accordingly, the undisputed record compels the conclusion that summary judgment is appropriate now.

Because DRL cannot dispute the fundamental substantive bases underlying Plaintiffs' request, DRL instead argues that the request is "premature" and "has already been decided" because Judge Waldor granted leave to file the antitrust counterclaims and ordered discovery on the counterclaims to proceed. D.I. 410 at 2-4. These arguments miss the fundamental point. As an initial matter, Plaintiffs' request has nothing to do with "trying to avoid discovery," as DRL contends. *Id.* at 1. To the contrary, Plaintiffs' proposed summary judgment motion would contribute to an efficient and accelerated resolution of this case by addressing issues that can be decided as a matter of law now, without the need for further, unnecessary discovery. Indeed, DRL's letter does not identify any discovery that it needs in order to respond to the proposed summary judgment motion (there is none) because Plaintiffs' contemplated motion poses a question that can be decided as a matter of law and the existing undisputed facts.<sup>1</sup>

In any event, because Judge Waldor denied Plaintiffs' request for a stay of discovery pending appeal of her order granting leave to file the antitrust counterclaims, Plaintiffs have fully and in good faith engaged on discovery. Judge Waldor ordered Indivior to conduct a massive document review in response to DRL and Alvogen's antitrust-related document requests. Indivior did so, substantially completing its production on July 1 of over two million documents produced to the FTC and DOJ in connection with investigations that purportedly form the basis for DRL's counterclaims.

Ultimately, whether discovery is complete or not is irrelevant and misses the point. Plaintiffs' request for leave to file summary judgment is not premature because the request does not depend on any remaining discovery. DRL does not (and cannot) dispute that objective baselessness is a question of law. And DRL cannot identify any discovery that could possibly change the outcome of the preliminary injunction proceedings, which is of record in this case and not in dispute. DRL also cannot deny that it described the "backdrop against which" the Court was operating in resolving Plaintiffs' preliminary injunction motion in June 2018, as including "an aggressive marketing campaign, telling patients that films were superior," alleged statements to the public that tablets "were unsafe for children," lawsuits challenging Indivior's allegedly anticompetitive practices by "the United States Department of Justice, 40 states, and a number of payors," and \$300 million that Indivior had "set aside ... for payments to the government to settle investigations and litigations due by 2020." **Exhibit 1** hereto (D.I. 111), at 145:20-147:18. Indeed, DRL's summary of its argument on the equitable factors during the preliminary injunction hearing vitiates any suggestion that the Court was somehow misled during the preliminary injunction proceedings: "What Indivior is asking your Honor to do is to extend the

---

<sup>1</sup> DRL cites the need for discovery on the "subjective intent to cause antitrust harm" (D.I. 410 at 4) but such discovery is not relevant to the proposed motion that will focus only on the objective baselessness prong of DRL's sham litigation claim.

Hon. Kevin McNulty, U.S.D.J.  
 August 11, 2020  
 Page 3

monopoly on Suboxone® films because it has to pay the government \$300 million to resolve claims that the monopoly it created on Suboxone® films was illegal and anti-competitive.” *Id.* at 164:15-165:2.

DRL’s argument that Plaintiffs’ request “has already been decided” is also wrong. Plaintiffs have appealed Judge Waldor’s order granting leave to file the counterclaims to Your Honor primarily because Judge Waldor’s decision did not address Plaintiffs’ futility challenge. The key issue in the futility context—whether DRL states a claim as a matter of law—is very similar to the legal issue ripe for resolution now on which Plaintiffs seek leave to move for summary judgment. The only difference is that Judge Waldor’s decision was governed by the more liberal standard of Rule 15, whereas the motion for summary judgment will be governed by the more stringent Rule 56 standard. The underlying question of objective baselessness—which is a question of law appropriate for resolution on summary judgment—remains the same. That is why granting leave would necessarily render Plaintiffs’ appeal of Judge Waldor’s order moot and save Your Honor the time of having to consider the objective baselessness prong of *Noerr-Pennington* multiple times.

DRL’s other arguments are also easily rejected. DRL is wrong that the assertion of the ’305 patent is “another claim” that “does not have any bearing” on DRL’s antitrust counterclaims. D.I. 410 at 3. To the contrary, Plaintiffs secured the preliminary injunction **because of** the merits of their patent positions and the well-established rights of exclusivity under their patents. What’s more, DRL has now confirmed that its counterclaims “focus only on Plaintiffs’ misconduct during the preliminary injunction proceedings before this Court.” D.I. 410 at 3 n.1. But, DRL does not show that dismembering the preliminary injunction decision and focusing only on the balance of equities would otherwise change the outcome of the preliminary injunction proceedings.

DRL’s argument that the guilty plea of nonparty Indivior Solutions, Inc. (“ISI”) “should have smoothed and expedited the path for the remaining discovery in this matter” (D.I. 410 at 1) is both bizarre and unsupported.<sup>2</sup> DRL does not show how the guilty plea bears on its counterclaims. Nor can it. ISI pled guilty to making false statements in 2012 when its Medical Affairs Manager represented to one Massachusetts state entity (MassHealth) that certain third-party data showed that film had the lowest incidence of unintended pediatric exposure when, in fact, that data showed that a tablet product had a lower incidence. **Exhibit 2** hereto, Information ¶ 24. ISI did not admit to any other allegations in the indictment, but the plea-related Resolution Agreement nonetheless resolved all potential criminal liability of Indivior Inc. and Indivior plc (and their subsidiaries, including ISI).<sup>3</sup> *See id.* at Resolution Agreement. DRL makes no effort to show that Indivior Solutions’ false statement to MassHealth in 2012—which was corrected in

---

<sup>2</sup> ISI is a wholly owned subsidiary of Indivior Inc.

<sup>3</sup> Indivior also resolved any civil liability to the government in a no-admission settlement with the FTC.

Hon. Kevin McNulty, U.S.D.J.  
August 11, 2020  
Page 4

2015—had any impact on DRL years later when it received FDA approval in June 2018,<sup>4</sup> nor that it could have impacted Your Honor’s preliminary injunction ruling.

In fact, DRL itself sought to persuade the Court during the preliminary injunction proceedings that Suboxone® film is a better product than the tablet. DRL proffered two experts who stated that Suboxone Film was superior to the tablet. One DRL expert explained his experience that “the best treatment option for most patients—in terms of likelihood of compliance and efficacy—is buprenorphine film, which is currently only available as a branded drug, Suboxone®.” Dkt. 90, ¶ 37. The other expert expressed her belief that Suboxone Film was superior to generic tablets, noting for “patients in my practice, the best treatment option is Suboxone film.” Dkt. 89, ¶ 22. And DRL’s own counsel represented to the Court that “the tablets don’t work” for some people, Dkt. 110, 207:25, and repeatedly highlighted that film products, as opposed to tablets, were necessary to save lives. *See* Dkt. 88 at 27; Dkt. 110 at 211:5–10; *id.* at 219:16–220:2; Ex. B, Appellants’ Corrected Non-Confidential Opening Brief, No. 18-2167, Dkt. 48, at 54-56 (Fed. Cir. July 20, 2018). Ultimately, even if the Court were to assume that DRL could somehow prove in this patent case the unproven allegations that the government has released, none of that would change the undisputed record that the Court issued the injunction against a “backdrop” that included extensive knowledge of alleged marketing misconduct by Indivior and DRL’s arguments about the superiority of film over tablets.<sup>5</sup>

\* \* \*

For the reasons above and those in Plaintiffs’ opening letter, we respectfully request that the Court grant Plaintiffs leave to file a summary judgment motion now on the antitrust counterclaims asserted by DRL. Thank you for Your Honor’s kind attention to this matter.

Respectfully yours,

  
William C. Baton

Exhibits

cc: The Honorable Cathy L. Waldor, U.S.M.J.  
All Counsel (via e-mail)

---

<sup>4</sup> ISI corrected the false statement to MassHealth by ISI’s Medical Affairs manager in December 2015 after the government had initiated its investigation. **Exhibit 2** at Information ¶ 27.

<sup>5</sup> The resolution of the criminal case with a plea by Indivior’s subsidiary relating only to statements to one state entity in 2012 should dispose of DRL’s antitrust counterclaims for a different reason: DRL represented to the Court during the hearing on its motion for leave to amend that its counterclaims would not necessitate “mini-trials” on the substance of the allegations in the federal indictment: “[t]his isn’t going to be a trial about the allegations in an indictment that has yet to be proven in a criminal context.” *See* D.I. 293 (Oct 29, 2019 Tr.) at 77:7-9. In light of these representations, Indivior has asked DRL whether it plans to withdraw its antitrust counterclaims. DRL’s refusal to do so will obviously then require this Court to address the counterclaims.

# **EXHIBIT 1**

**FILED UNDER  
SEAL**

# **EXHIBIT 2**

Attachment 3 to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc

Plea Agreement

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF VIRGINIA  
ABINGDON

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	Violation:
INDIVIOR SOLUTIONS, INC.	)	18 U.S.C. § 1035
	)	

**PLEA AGREEMENT**

INDIVIOR SOLUTIONS, INC. (EIN: 52-2069631) ("INDIVIOR SOLUTIONS") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. **CHARGE TO WHICH INDIVIOR SOLUTIONS IS PLEADING GUILTY AND WAIVER OF RIGHTS**

INDIVIOR SOLUTIONS will enter a plea of guilty to Count One of an Information charging it with knowingly and willfully making materially false statements relating to health care matters in violation of Title 18, United States Code, Section 1035. The Information involves charges brought by the United States Attorney as opposed to one returned by a Grand Jury. INDIVIOR SOLUTIONS hereby waives and gives up its right to be charged by Indictment and have a Grand Jury vote on its probable guilt.

The parties agree and stipulate that INDIVIOR SOLUTIONS is liable for a maximum statutory fine of \$245,000,000 (two hundred forty-five million dollars) pursuant to Title 18, United States Code, Section 3571(d), plus a period of probation of no more than five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(1). In addition, INDIVIOR SOLUTIONS' assets are subject to forfeiture. INDIVIOR SOLUTIONS understands fees may be imposed to pay for probation and there will be a \$400 (four hundred dollars) special assessment, pursuant to Title 18, United States Code, Section 3013(a)(2)(B). INDIVIOR SOLUTIONS' attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before INDIVIOR SOLUTIONS could be found guilty as charged.

INDIVIOR SOLUTIONS acknowledges INDIVIOR SOLUTIONS has had all of its rights explained to it. INDIVIOR SOLUTIONS expressly recognizes that, as a corporation, INDIVIOR SOLUTIONS may have the following constitutional rights and by voluntarily pleading guilty INDIVIOR SOLUTIONS knowingly waives and gives up these valuable constitutional rights:

Plea Agreement  
United States v. Indivior Solutions, Inc.

Authorized Corporate Officer's Initials:

*JR*



The right to plead not guilty and persist in that plea.  
The right to a speedy and public jury trial.  
The right to assistance of counsel at that trial and in any subsequent appeal.  
The right to remain silent at trial.  
The right to testify at trial.  
The right to confront and cross-examine witnesses.  
The right to present evidence and witnesses.  
The right to compulsory process of the court.  
The right to compel the attendance of witnesses at trial.  
The right to be presumed innocent.  
The right to a unanimous guilty verdict.  
The right to appeal a guilty verdict.

INDIVIOR SOLUTIONS is pleading guilty as described above because INDIVIOR SOLUTIONS is in fact guilty and because INDIVIOR SOLUTIONS believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement and the related documents, described herein, in exchange for its plea of guilty. INDIVIOR SOLUTIONS agrees all of the matters set forth in the Information are true and correct.

INDIVIOR SOLUTIONS understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

## **2. FACTUAL REPRESENTATIONS**

INDIVIOR SOLUTIONS stipulates the facts and allegations set forth in the Information to which it is pleading guilty are true and correct.

## **3. SENTENCING PROVISIONS**

The parties agree the 2018 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize.

The parties agree the U.S.S.G. applies to any guidelines calculation made pertaining to the offense and stipulate that the following guideline sections are applicable to the conduct:

2B1.1(a)(2)	6	Base Offense Level
2B1.1(b)(1)(M)	+ 24	Gain More Than \$65M and Not Greater Than \$150M
2B1.1(b)(7)	+ 4	Loss to Government Health Care Program of More Than \$20M

The parties agree and stipulate a term of probation for up to five years will be imposed. The Court will determine what terms of probation are appropriate and the parties will be free to argue for what terms are included. INDIVIOR SOLUTIONS understands



and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, INDIVIOR SOLUTIONS will be free to withdraw its guilty plea. In the event the Court refuses to accept this Plea Agreement and INDIVIOR SOLUTIONS withdraws its guilty plea within ten (10) days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may pursue any or all of the remedies set forth in the Plea Agreement or Resolution Agreement, as if INDIVIOR SOLUTIONS had failed to comply with a term of the Plea Agreement or as if Indivior Inc. or Indivior plc had failed to comply with a term of the Resolution Agreement.

#### 4. FINANCIAL RESPONSIBILITIES

##### a. Financial Obligations

In addition to the mandatory assessment of \$400 (four hundred dollars), INDIVIOR SOLUTIONS, as part of the Resolution Agreement attached as Exhibit A, agrees to make the following payments, as directed by the United States:

TABLE OF PAYMENTS BY INDIVIOR SOLUTIONS AND GUARANTEED BY INDIVIOR INC. AND INDIVIOR PLC				
		Designation of Payments		
Due Date	Payment Due	Court's Discretionary Fund	Forfeiture	MFCU
Put in Escrow Prior to INDIVIOR SOLUTIONS Pleading Guilty#	\$ 54,000,000	\$ 31,000,000	\$ 22,000,000	\$ 1,000,000
1/15/2022	\$ 25,000,000	\$ 25,000,000		
1/15/2023	\$ 25,000,000	\$ 25,000,000		
1/15/2024	\$ 25,000,000	\$ 25,000,000		
1/15/2025	\$ 25,000,000	\$ 25,000,000		
1/15/2026	\$ 25,000,000	\$ 25,000,000		
1/15/2027	\$ 25,000,000	\$ 25,000,000		
12/15/2027	\$ 86,000,000	\$ 64,000,000	\$ 22,000,000	
<b>TOTAL</b>	<b>\$ 290,000,000</b>	<b>\$ 245,000,000</b>	<b>\$ 44,000,000</b>	<b>\$ 1,000,000</b>

#Payments due prior to Indivior Solutions pleading guilty will be placed in an escrow account. Within 3 (three) days of the Court imposing sentence, the escrow funds will be disbursed as set forth herein. For all of the escrowed amounts, in addition to the escrowed payments, INDIVIOR SOLUTIONS will pay, and Indivior, Inc. and Indivior plc will guarantee payment of, interest at the rate of 1.25% (one and one quarter percent) per annum calculated from April 9, 2020, to the time payment is made from the escrow account. The interest paid on the escrowed funds will not be credited toward the total amount due and will make the Court's Discretionary Fund greater than \$245,000,000 (two hundred forty-five million dollars).

INDIVIOR SOLUTIONS agrees and understands none of the money paid pursuant to this Plea Agreement will be returned if the Plea Agreement is accepted by the Court.

INDIVIOR SOLUTIONS must notify the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") as soon as reasonably practicable, in writing, of any event (including, but not limited to, sale, merger, dissolution, etc.) that would jeopardize its ability to pay any amounts under this Plea Agreement.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), INDIVIOR SOLUTIONS will notify the Court of any material change in INDIVIOR SOLUTIONS' economic circumstances that might affect INDIVIOR SOLUTIONS' ability to pay any amounts payable under this Plea Agreement.

**b. Forfeiture**

INDIVIOR SOLUTIONS agrees to the entry of a forfeiture money judgment in an amount not less than \$44,000,000 (forty-four million dollars) and not more than \$289,000,000 (two hundred eighty-nine million dollars) ("Forfeiture Money Judgment") in United States currency. INDIVIOR SOLUTIONS will not contest such forfeiture. Any amount of forfeiture above \$44,000,000 (forty-four million dollars) ordered by the Court will be taken from the Court's Discretionary Fund. The schedule of payment of forfeiture shall be as set forth in the table above.

INDIVIOR SOLUTIONS acknowledges and agrees some of the proceeds of the crime cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, INDIVIOR SOLUTIONS agrees the government is entitled to forfeit as substitute assets any other assets of INDIVIOR SOLUTIONS up to the value of the now missing directly forfeitable assets, pursuant to 21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment (attached as Exhibit C) shall satisfy any and all forfeiture obligations that INDIVIOR SOLUTIONS may have as a result of this guilty plea. INDIVIOR SOLUTIONS consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

INDIVIOR SOLUTIONS agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. INDIVIOR SOLUTIONS agrees to forfeit all interest in these funds as provided in the payment schedule set forth in this Plea Agreement and to take whatever steps are necessary to pass clear title of these funds to the United States.

INDIVIOR SOLUTIONS agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. INDIVIOR SOLUTIONS agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgment in any administrative or judicial proceeding.

INDIVIOR SOLUTIONS understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. INDIVIOR SOLUTIONS freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. INDIVIOR SOLUTIONS further understands and agrees the forfeiture ordered by the Court as part of the total criminal payment of \$290,000,000 (two hundred ninety million dollars) that may be imposed pursuant to this agreement is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

**c. Court's Discretionary Fund**

INDIVIOR SOLUTIONS agrees it will submit payments totaling \$245,000,000 (two hundred forty-five million dollars) [plus interest accrued on the first payment] in accordance with the table set forth above, to be allocated to a fine, any forfeiture above \$44,000,000 (forty-four million dollars), and, if the Court deems it appropriate, restitution. The Court has absolute discretion to determine how this money should be allocated among these items. If the Court deems restitution to be appropriate, pursuant to 18 U.S.C. 3663(a)(3), the parties agree the Court may order restitution in any manner it deems appropriate. These \$245,000,000 (two hundred forty-five million dollars) in payments are designated in the table above as the "Court's Discretionary Fund."

**d. Virginia Medicaid Fund**

INDIVIOR SOLUTIONS agrees it will submit a payment of \$1,000,000 (one million dollars) to the Virginia Medicaid Fraud Control Unit to be used for the 25% state match of the Medicaid Fraud Control Unit grant in accordance with the table set forth above.

**e. Financial Obligations are Not Dischargeable**

The parties warrant that, in evaluating whether to execute this Agreement, they have (a) intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to INDIVIOR SOLUTIONS, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to, and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which INDIVIOR SOLUTIONS was or became indebted to on or after the Agreement Date, within the meaning of 11 U.S.C. § 548(a)(1). INDIVIOR SOLUTIONS agrees its obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and INDIVIOR SOLUTIONS shall not argue or



otherwise take the position in any such case, action, or proceeding that (1) INDIVIOR SOLUTIONS' obligations under this Agreement may be avoided under 11 U.S.C. § 547; (2) INDIVIOR SOLUTIONS was insolvent at the time this Agreement was entered into; or (3) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to INDIVIOR SOLUTIONS. INDIVIOR SOLUTIONS acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement. INDIVIOR SOLUTIONS agrees all amounts payable under this agreement are not dischargeable in bankruptcy and shall be considered debt for a fine, penalty, or forfeiture payable to and for the benefit of a governmental unit pursuant to 11 U.S.C. § 523(a)(7). INDIVIOR SOLUTIONS expressly admits and acknowledges that (a) INDIVIOR SOLUTIONS' actions described herein were misrepresentations, fraudulent omissions, and/or deceptive conduct; (b) INDIVIOR SOLUTIONS knew these actions were false and/or deceptive; (c) INDIVIOR SOLUTIONS took these actions with an intent to deceive the United States of America; (d) the United States of America justifiably relied on these actions; and (e) this reliance proximately caused damage to the United States of America. INDIVIOR SOLUTIONS agrees all forfeiture amounts ordered by the Court represent criminal proceeds subject to forfeiture, and as such, the Government's interest in those proceeds arose on the date INDIVIOR SOLUTIONS received those proceeds pursuant to 21 U.S.C. 853(c).

## **5. ADDITIONAL OBLIGATIONS**

Unless the Court rejects this Plea Agreement and, as a result, INDIVIOR SOLUTIONS withdraws its plea, INDIVIOR SOLUTIONS agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; and (4) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

INDIVIOR SOLUTIONS will not, through its present or future directors, officers, employees, or agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Agreement or its attachments. If INDIVIOR SOLUTIONS makes a public statement that in whole or in part contradicts any such statement or provision, INDIVIOR SOLUTIONS may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by INDIVIOR SOLUTIONS' directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) INDIVIOR SOLUTIONS' websites. Notwithstanding the above, INDIVIOR SOLUTIONS may avail itself of any legal or factual arguments available in defending litigation brought by a party other than the United States. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal,

regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

Except as may otherwise be agreed by the parties in connection with a particular transaction, INDIVIOR SOLUTIONS agrees if, during the term of this Agreement, it undertakes any material change in corporate form, including if it sells, merges, or transfers business operations material to INDIVIOR SOLUTIONS' consolidated operations as they exist as of the date of this Agreement, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. INDIVIOR SOLUTIONS shall provide notice to the USAO-WDVA and the United States Department of Justice's Consumer Protection Branch ("CPB") at least 30 (thirty) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict INDIVIOR SOLUTIONS from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the USAO-WDVA and CPB.

**6. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT**

If the Court accepts this Plea Agreement, INDIVIOR SOLUTIONS agrees INDIVIOR SOLUTIONS will not appeal the conviction or sentence imposed. INDIVIOR SOLUTIONS is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). INDIVIOR SOLUTIONS expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. INDIVIOR SOLUTIONS understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, INDIVIOR SOLUTIONS may file a cross appeal of that same sentence. INDIVIOR SOLUTIONS agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

**7. INFORMATION ACCESS WAIVER**

INDIVIOR SOLUTIONS waives all rights, whether asserted directly or by a representative, to request or receive from the United States Department of Justice, United States Food and Drug Administration – Office of Criminal Investigations, United States Department of Health and Human Services – Office of Inspector General, United States

Postal Service – Office of Inspector General, and Virginia Office of the Attorney General Medicaid Fraud Control Unit any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, the Privacy Act of 1974, 5 U.S.C. § 552a, or the Virginia Freedom of Information Act, Va. Code § 2.2-3700- 3714.

**8. ADMISSIBILITY OF STATEMENTS**

INDIVIOR SOLUTIONS understands any statements made on its behalf (including, but not limited to, this Plea Agreement, the Information, and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against INDIVIOR SOLUTIONS by the United States in this or any other proceeding. INDIVIOR SOLUTIONS knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, INDIVIOR SOLUTIONS withdraws its plea, INDIVIOR SOLUTIONS will not be bound by the waivers set forth in this section of the Plea Agreement.

**9. COMPLETION OF PROSECUTION**

The parties agree they are bound by Paragraph 22 of the Resolution Agreement.

**10. LIMITATION OF PLEA AGREEMENT**

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

**11. COMPLIANCE AND REMEDIAL MEASURES**

The parties agree they are bound by the terms of the Resolution Agreement.

**12. COOPERATION**

INDIVIOR SOLUTIONS will fully cooperate with all investigations and prosecutions, if any, by the Department of Justice related, in any way, to Suboxone or any other drug marketed or promoted by INDIVIOR SOLUTIONS. INDIVIOR SOLUTIONS' cooperation in the investigation and prosecution of individuals and entities pursuant to this paragraph includes, but is not limited to, using best efforts promptly to secure the attendance and testimony of any current or former officer, director, agent, or employee of INDIVIOR SOLUTIONS at any meeting or interview or before the grand jury or at any trial or other court proceeding; and truthfully disclosing all factual information, documents,



records, or other tangible evidence not protected by a valid claim of privilege or work product. INDIVIOR SOLUTIONS' cooperation is subject to applicable laws and regulations, including relevant data privacy and national security laws and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine. INDIVIOR SOLUTIONS expressly understands, to the extent there is conduct disclosed by INDIVIOR SOLUTIONS that does not relate to Suboxone or Subutex, such conduct will not be exempt from prosecution and is not within the scope of the non-prosecution terms of this Agreement.

**13. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT**

INDIVIOR SOLUTIONS understands if: (1) INDIVIOR SOLUTIONS attempts to withdraw its plea (in the absence of the Court refusing to accept this Plea Agreement); (2) INDIVIOR SOLUTIONS fails to comply with any provision of this Plea Agreement; (3) Indivior Inc. or Indivior plc fail to comply with any provision of the Resolution Agreement (4) INDIVIOR SOLUTIONS' conviction is set aside, for any reason; and/or (5) INDIVIOR SOLUTIONS fails to execute all required paperwork prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement and/or the Resolution Agreement void; (b) file against any entity, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement or the Resolution Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement or the Resolution Agreement, and (e) take any other action provided for under this Plea Agreement, the Resolution Agreement, or by statute, regulation, or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, INDIVIOR SOLUTIONS will still be bound by its obligations under this Plea Agreement. INDIVIOR SOLUTIONS hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. INDIVIOR SOLUTIONS hereby waives any statute of limitations argument as to any such charges.

**14. EXCLUSION**

INDIVIOR SOLUTIONS understands that as a consequence of pleading guilty pursuant to this Agreement the United States Department of Health and Human Services ("HHS") will exclude INDIVIOR SOLUTIONS from participating in Federal health care programs, pursuant to 42 U.S.C. §§ 1320a-7(a)(1). INDIVIOR SOLUTIONS will not contest its exclusion.



**15. EFFECTIVE REPRESENTATION**

INDIVIOR SOLUTIONS has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, INDIVIOR SOLUTIONS has no dissatisfaction or complaint with its attorneys' representation. INDIVIOR SOLUTIONS agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint INDIVIOR SOLUTIONS may have with its attorneys' representation.

**16. EFFECT OF INDIVIOR SOLUTIONS' SIGNATURE**

INDIVIOR SOLUTIONS understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. INDIVIOR SOLUTIONS understands the United States has not accepted INDIVIOR SOLUTIONS' offer until the authorized representative of the United States has signed this Plea Agreement.

**17. GENERAL UNDERSTANDINGS**

INDIVIOR SOLUTIONS understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

INDIVIOR SOLUTIONS understands the United States and INDIVIOR SOLUTIONS retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

INDIVIOR SOLUTIONS willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

INDIVIOR SOLUTIONS understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

INDIVIOR SOLUTIONS has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, which is part of a larger resolution set forth in the Resolution Agreement (attached as Exhibit A), in exchange for its plea of guilty. INDIVIOR SOLUTIONS understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. INDIVIOR SOLUTIONS understands INDIVIOR SOLUTIONS will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing and the Resolution Agreement and its attachments are the complete and only agreements between the United States and INDIVIOR SOLUTIONS concerning resolution of this matter. In addition, INDIVIOR SOLUTIONS has no objection to the filing of the Information (Exhibit B). The agreements and documents listed in this section

set forth the entire understanding between the parties and constitute the complete agreement between the USAO-WDVA and INDIVIOR SOLUTIONS and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and INDIVIOR SOLUTIONS. INDIVIOR SOLUTIONS consents to public disclosure of all of the agreements and other documents referenced in this section.

INDIVIOR SOLUTIONS has consulted with its attorneys and fully understands its rights. INDIVIOR SOLUTIONS has read this Plea Agreement and carefully reviewed every part of it with its attorneys. INDIVIOR SOLUTIONS understands this Plea Agreement and INDIVIOR SOLUTIONS voluntarily agrees to it. Being aware of all of the possible consequences of its plea, INDIVIOR SOLUTIONS has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

- (1) The Officer is fully authorized to enter into this Plea Agreement on behalf of INDIVIOR SOLUTIONS;
- (2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with INDIVIOR SOLUTIONS' Board of Directors;
- (3) INDIVIOR SOLUTIONS understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;
- (4) INDIVIOR SOLUTIONS is fully satisfied with INDIVIOR SOLUTIONS' attorneys' representation during all phases of this case;
- (5) INDIVIOR SOLUTIONS is freely and voluntarily pleading guilty in this case;
- (6) INDIVIOR SOLUTIONS is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and
- (7) INDIVIOR SOLUTIONS understands it is waiving its right to appeal the judgment and conviction in this case.

INDIVIOR SOLUTIONS acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by INDIVIOR SOLUTIONS' Board of Directors authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of INDIVIOR SOLUTIONS is attached as Addendum 1.

Attachment 3 to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc

Plea Agreement

**Agreed to:**

**Indivior Solutions, Inc.**

BY: \_\_\_\_\_

  
Javier Rodriguez  
Authorized Corporate Representative  
for Indivior Solutions, Inc.

DATE

7/24/20

Counsel has fully explained to the Board of Directors of INDIVIOR SOLUTIONS the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the U.S.S.G.; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. INDIVIOR SOLUTIONS understands the terms and conditions of this Plea Agreement, and INDIVIOR SOLUTIONS' decision to enter into this Plea Agreement is knowing and voluntary. INDIVIOR SOLUTIONS' execution of and entry into the Plea Agreement is done with Counsel's consent.

\_\_\_\_\_  
James R. Wooley

Counsel for Indivior Solutions, Inc.

DATE

7/24/20

\_\_\_\_\_  
Thomas W. Beimers

Counsel for Indivior Solutions, Inc.

DATE

7/24/20

*Attachment 3 to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc*

Plea Agreement

**The United States Attorney's Office for the Western District of Virginia:**

BY: \_\_\_\_\_

DANIEL P. BUBAR

DATE \_\_\_\_\_

*Attorney for the United States,*

*Acting Under Authority Conferred by 28 U.S.C. Section 515*

ALBERT P. MAYER

*Trial Attorney, Department of Justice, Civil Division,*

*Commercial Litigation Branch*

RANDY RAMSEYER

*Assistant United States Attorney*

KRISTIN L. GRAY

JOSEPH S. HALL

JANINE M. MYATT

*Special Assistant United States Attorneys / Assistant Attorneys General,*

*Medicaid Fraud Control Unit, Virginia Office of the Attorney General*

GARTH W. HUSTON

*Special Assistant United States Attorney / Attorney, Federal Trade Commission*

CAROL L. WALLACK

*Trial Attorney, Department of Justice, Civil Division,*

*Commercial Litigation Branch*

**The United States Department of Justice, Consumer Protection Branch:**

BY: \_\_\_\_\_

GUSTAV W. EYLER

DATE \_\_\_\_\_

*Director*

JILL P. FURMAN

*Deputy Director*

CHARLES J. BIRO

MATTHEW J. LASH

*Trial Attorneys*

*JR*



*Attachment 3 to Resolution Agreement*  
*United States v. Indivior Inc. and Indivior plc*

Plea Agreement

**The United States Attorney's Office for the Western District of Virginia:**

BY:

  
DANIEL P. BUBAR

7/23/20  
DATE

*Attorney for the United States,*  
*Acting Under Authority Conferred by 28 U.S.C. Section 515*

ALBERT P. MAYER

*Trial Attorney, Department of Justice, Civil Division,*  
*Commercial Litigation Branch*

RANDY RAMSEYER

*Assistant United States Attorney*

KRISTIN L. GRAY

JOSEPH S. HALL

JANINE M. MYATT

*Special Assistant United States Attorneys / Assistant Attorneys General,*  
*Medicaid Fraud Control Unit, Virginia Office of the Attorney General*

GARTH W. HUSTON

*Special Assistant United States Attorney / Attorney, Federal Trade Commission*

CAROL L. WALLACK

*Trial Attorney, Department of Justice, Civil Division,*  
*Commercial Litigation Branch*

**The United States Department of Justice, Consumer Protection Branch:**

BY:

  
GUSTAV W. EYLER

7/23/20  
DATE

*Director*

JILL P. FURMAN

*Deputy Director*

CHARLES J. BIRO

MATTHEW J. LASH

*Trial Attorneys*

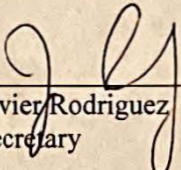
*Plea Agreement*  
*United States v. Indivior Solutions, Inc.*

*Authorized Corporate Officer's Initials: \_\_\_\_\_*

INDIVIOR SOLUTIONS, INC.  
OFFICER'S CERTIFICATE

The undersigned, Javier Rodriguez, the Secretary and corporate representative of Indivior Solutions, Inc., ("Indivior Solutions") a Delaware corporation and wholly owned indirect subsidiary of Indivior PLC, DOES HEREBY CERTIFY that attached hereto as Exhibit A is a true, correct and complete copy of the resolutions approved by the Board of Directors of Indivior Solutions, dated July 23, 2020 authorizing Javier Rodriguez to execute and deliver on behalf of Indivior Solutions the Waiver of Indictment and Plea Agreement, and the Agreed Order of Forfeiture, between the United States of America and Indivior Solutions Inc., to resolve the matter of *United States v. Indivior*, 1:19-Cr-016 (JPJ) (W.D. Va.) and certain civil and regulatory matters described in the Resolution Agreement, which resolution has not been amended or rescinded as of the date hereof.

July 24, 2020

  
\_\_\_\_\_  
Javier Rodriguez  
Secretary

# Exhibit A



UNANIMOUS WRITTEN CONSENT OF  
THE BOARD OF DIRECTORS OF INDIVIOR SOLUTIONS, INC.

WHEREAS, Indivior Solutions, Inc. ("Indivior Solutions"), is a Delaware corporation and wholly owned subsidiary of Indivior Inc., a Delaware corporation, and a wholly owned indirect subsidiary of Indivior PLC, a company registered in England and Wales.

WHEREAS, Indivior Inc., and Indivior PLC were charged with offenses in an indictment and superseding indictment in the Western District of Virginia captioned *United States v. Indivior Inc. and Indivior PLC*, 1:19-Cr-016 (JPJ) (the "Charged Case").

WHEREAS, the Charged Case is being prosecuted by the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and the United States Department of Justice's Consumer Protection Branch ("CPB").

WHEREAS, the USAO-WDVA and CPB have agreed to resolve the Charged Case on the terms set forth in the Resolution Agreement, and the documents referenced therein, which includes dismissal of the Charged Case and a Plea Agreement between USAO-WDVA, CPB and Indivior Solutions that would require Indivior Solutions to plead guilty to one count of making false statements relating to health care matters, in violation of Title 18, United States Code, Section 1035.

WHEREAS, the Indivior PLC and Indivior Inc. Board of Directors has decided on unanimous consent to resolve the Charged Case pursuant to the Resolution Agreement.

WHEREAS, Indivior PLC and Indivior Inc., have been in discussions with certain parties and governmental authorities to resolve certain civil and regulatory matters arising from the marketing, sale, promotion and distribution of Suboxone Film in the United States.

WHEREAS, the Board of Directors has unanimously agreed to resolve these certain civil and regulatory matters as set forth in the Resolution Agreement and the documents referenced therein.

IT IS HEREBY RESOLVED, that the waiver of indictment ("Waiver of Indictment") by Indivior Solutions, in the form presented to the Board of Directors at the meeting on July 23, 2020 is approved; and further

RESOLVED, that the Plea Agreement between the USAO-WDVA, CPB and Indivior Solutions (the "Plea Agreement") in the form presented to the Board of Directors at the meeting on July 23, 2020 is approved; and further

RESOLVED, that the Stipulation for Compromise Settlement between the United States of America and Indivior Solutions (the "Stipulation for Compromise Settlement") in the form presented to the Board of Directors is approved; and further



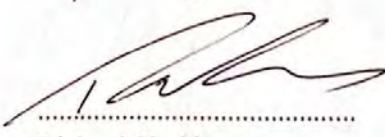
RESOLVED, that the Agreed Order of Forfeiture between the United States of America and Indivior Solutions (the "Agreed Order of Forfeiture") in the form presented to the Board of Directors is approved; and further

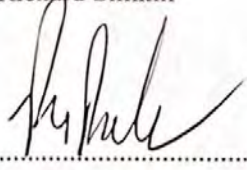
RESOLVED, that Javier Rodriguez as the Secretary and corporate representative of Indivior Solutions, is hereby authorized and directed to execute and deliver in the name and on behalf of Indivior Solutions the Waiver of Indictment, Plea Agreement, the Stipulation for Compromise Settlement, and the Agreed Order of Forfeiture (hereinafter collectively referred to as the "Settlement Documents"), each in the form or substantially in the form presented to the Indivior Solutions Board of Directors, with such changes, additions and modifications thereto as he shall approve, such approval to be conclusively evidenced by his execution and delivery thereof; and further

RESOLVED, that Javier Rodriguez as the Secretary and corporate representative of Indivior Solutions, is hereby authorized and directed to make, execute and deliver, or cause to be made, executed and delivered, all such agreements, documents, instruments and other papers, and to do or cause to be done on behalf of Indivior Solutions, all such acts, as he may deem necessary or appropriate to carry out the purposes and intent of the foregoing resolutions, including, but not limited to, appearing on behalf of Indivior Solutions in the United States District Court for the Western District of Virginia, Abingdon Division, in order to make any statement or statements on behalf of Indivior Solutions he deems appropriate in connection with the waiver of indictment and guilty plea of Indivior Solutions in accordance with the Settlement Documents.

IN WITNESS WHEREOF, the undersigned Directors have duly executed this Unanimous Written Consent as of this 23rd day of July 2020

  
Javier Rodriguez

  
Richard Simkin

 7/23/2020  
Ryan Preblich

There is No Attachment 3 (Exhibit A)

Attachment 3 (Exhibit B) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc

Information

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF VIRGINIA  
ABINGDON**

<b>UNITED STATES OF AMERICA</b>	)	
	)	<b>Criminal No.</b>
<b>v.</b>	)	
	)	<b>Violations:</b>
<b>INDIVIOR SOLUTIONS, INC.</b>	)	<b>18 U.S.C. § 1035</b>
	)	

**INFORMATION**

**COUNT ONE  
False Statements Relating to Health Care Matters  
18 U.S.C. § 1035**

The Attorney for the United States<sup>1</sup> charges that:

**DEFENDANT**

1. INDIVIOR SOLUTIONS, INC. (hereinafter “INDIVIOR SOLUTIONS”) is a wholly owned subsidiary of Indivior Inc., which was previously known as Reckitt Benckiser Pharmaceuticals Inc. (“RBP”). INDIVIOR SOLUTIONS was a division of RBP until it became a subsidiary corporation in September 2013. INDIVIOR SOLUTIONS is a Delaware corporation headquartered in Richmond, Virginia.

2. At times relevant to this Information, INDIVIOR SOLUTIONS was engaged in the pharmaceutical business throughout the United States, including in the Western District of Virginia. INDIVIOR SOLUTIONS’ business included marketing, promotion, field sales, managed-care sales, and field-medical functions for drugs containing buprenorphine, an opioid, under brand names including Suboxone and Subutex.

<sup>1</sup> Authority conferred by 28 U.S.C. § 515.

3. Until December 2014, RBP and INDIVIOR SOLUTIONS were subsidiaries of Company A.

### **HEALTH CARE BENEFIT PROGRAMS**

4. Medicaid is a health care benefit program under Title 18, United States Code, Section 24(b) that was administered by agencies of the various states to provide health care benefits and services to those who qualified. Medicaid is funded jointly by the states and by CMS and paid for certain prescription drugs for Medicaid beneficiaries.

5. MassHealth is the name of the Commonwealth of Massachusetts Medicaid program.

### **SUBOXONE TABLET AND SUBUTEX TABLET**

6. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continued taking opioids under medical supervision to avoid or reduce withdrawal symptoms while they sought to recover. The only opioid approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take at home) was buprenorphine, a Schedule III controlled substance under the Controlled Substances Act.

7. On or about October 8, 2002, RBP received approval from the Food and Drug Administration ("FDA") for the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). The FDA designated both as orphan drugs, meaning the FDA committed not to approve any competitor drug for seven years (the "exclusivity period").

8. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but it could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps.

9. Subutex Tablet was similar to Suboxone Tablet, but it did not include naloxone. It was intended for induction and certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps.

### **SUBOXONE FILM**

10. In 2007, as Suboxone Tablet and Subutex Tablet neared the end of their period of exclusivity, RBP began developing a new buprenorphine-containing drug for use in opioid addiction/dependence treatment: Suboxone Sublingual Film (“Suboxone Film”).

11. Like Suboxone Tablet, Suboxone Film was a combination of buprenorphine and naloxone, but because aspects of the film formulation were patented, it arguably had patent protection.

12. Suboxone Film differed from Suboxone Tablet in that (among other things) it has a thin form; sticks to the tongue/mouth; dissolves more rapidly; has potentially greater relative bioavailability at certain doses (as stated in the FDA-approved label); is formulated to taste better; and is packaged in individually wrapped, child-resistant foil pouches.



13. In August 2010, RBP received approval from the FDA to market Suboxone Film for use in the treatment of opioid addiction/dependence.

14. At times relevant to this Information, INDIVIOR SOLUTIONS marketed Suboxone Film to physicians and healthcare programs throughout the United States, including the Western District of Virginia

### **PEDIATRIC EXPOSURE RISK**

15. Suboxone Tablet, Subutex Tablet, and Suboxone Film, like many other drugs, carry a risk to children who take them by accident, sometimes called “unintended pediatric exposure.” This risk of unintended pediatric exposure is identified in the Important Safety Information in Suboxone’s FDA-approved labeling, on its package, and in a Medication Guide and Physician Brochure with instructions on safe storage of the drug.

16. INDIVIOR SOLUTIONS and others received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. During 2012 and thereafter, the data were analyzed by the Researched Abuse, Diversion, and Addiction-Related Surveillance System (“RADARS”) for rates and trends.

17. INDIVIOR SOLUTIONS used RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film. Specifically, INDIVIOR SOLUTIONS used RADARS analyses to assert that Suboxone Film provided greater protection against unintended pediatric exposure than other, similar drugs.



## **MATERIALLY FALSE STATEMENTS TO MASSHEALTH OFFICIALS**

18. Before in or around December 2012, Suboxone Film was not a preferred drug on the MassHealth formulary and had restrictions on approval for reimbursement. To increase sales of Suboxone Film, INDIVIOR SOLUTIONS employees and agents sought to persuade MassHealth that Suboxone Film had safety benefits compared to other, similar drugs, in an effort to make Suboxone Film a preferred drug on the MassHealth formulary and boost profits.

19. On or about May 17, 2011, a purported physician, acting at the behest of INDIVIOR SOLUTIONS State Government Affairs employees submitted an Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger, stating that Suboxone Film was “preventing diversion, recidivism, and the accidental death of inquisitive children,” and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were “engaging in 21<sup>st</sup> century biological warfare, no different than giving small pox infected blankets to the Indians.”

20. On or about June 23, 2011, the same purported physician, again acting at the behest of INDIVIOR SOLUTIONS State Government Affairs employees, sent an unsubstantiated email to MassHealth officials stating, “there is less opportunity for diversion with” Suboxone Film, “there is less chance that a curious child will ingest the film,” and “the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond’s filibuster in opposition of the Civil Rights Act of 1957.” The purported physician subsequently emailed the INDIVIOR SOLUTIONS State Government Affairs employees, seeking a \$30,000 donation to his foundation and a Harley-Davidson Road

King motorcycle as payment. The INDIVIOR SOLUTIONS State Government Affairs employees declined to make such payments.

21. On or about October 9, 2012, INDIVIOR SOLUTIONS Medical Affairs Manager met with a MassHealth official, and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. After the meeting, the INDIVIOR SOLUTIONS Medical Affairs Manager asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

22. The next day, on or about October 10, 2012, RADARS provided the INDIVIOR SOLUTIONS Medical Affairs Manager with the Massachusetts-specific analysis. It stated the rates of unintended pediatric exposure in Massachusetts for three categories of drugs: Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets such as Subutex Tablet (sometimes called “mono tablets”). It stated that in Massachusetts there were 1.8 exposures per 10,000 units for buprenorphine-only tablets such as Subutex Tablet, 3.3 exposures per 10,000 units for Suboxone Tablets, and 2.7 exposures per 10,000 units for Suboxone Film. These data showed that buprenorphine-only tablets like Subutex Tablet—which are packaged in bottles with child-resistant caps, in the same manner as Suboxone Tablet and many other drugs—had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts.

23. Upon receiving the analysis, the INDIVIOR SOLUTIONS Medical Affairs Manager asked RADARS (copying RBP’s Global Medical Director) if she could “just add

*Attachment 3 (Exhibit B) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc*

Information

the mono and combination tablets to see the difference from film.” However, adding the rates together would not provide an accurate calculation.

24. On or about October 16, 2012, the INDIVIOR SOLUTIONS Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained a calculation of the unintended pediatric exposure data for Massachusetts that in fact added the two tablet rates together. Further, the INDIVIOR SOLUTIONS Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS, when in fact, she had not received them from RADARS, but had done them herself. The INDIVIOR SOLUTIONS Medical Affairs Manager stated to the MassHealth official, and her calculations appeared to show, that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts, when in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts. The INDIVIOR SOLUTIONS Medical Affairs Manager then forwarded this email to RBP’s Global Medical Director, stating that she sent it to “help us get some movement in Mass.”

25. Subsequently, the INDIVIOR SOLUTIONS Medical Affairs Manager received additional unintended pediatric exposure data that did not show that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts, and did not provide it to MassHealth. At an RBP corporate conference, the INDIVIOR SOLUTIONS Medical Affairs Manager told other INDIVIOR SOLUTIONS employees that her rationale for withholding the additional data from MassHealth was, “don’t ask, don’t tell.”

*Exhibit B to Plea Agreement  
United States v. Indivior Solutions, Inc.*

*Authorized Corporate Officer's Initials:*

*JR*

26. In or about December 2012, MassHealth issued a press release announcing that it would “provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age,” and citing to INDIVIOR SOLUTIONS’ nationwide pediatric exposure rate data.

27. INDIVIOR SOLUTIONS failed to correct its inaccurate, false, and misleading statement made to MassHealth about unintended pediatric exposure in Massachusetts until December 2015, after the government had seized documents related to the false statements in a search warrant executed at RBP’s Richmond, Virginia, headquarters. During an intervening period between December 2012 and December 2015, MassHealth reimbursed at least a portion of the cost for Suboxone Film prescriptions written for certain of its beneficiaries, all to the benefit of INDIVIOR SOLUTIONS.

28. Therefore on dates set forth in this Information, in the Western District of Virginia and elsewhere, the defendant

**INDIVIOR SOLUTIONS, INC.**

knowingly and willfully made materially false statements to MassHealth in connection with the delivery of and payment for health care benefits, items, and services, all in violation of Title 18, United States Code, Section 1035.

**NOTICE OF FORFEITURE**

1. Upon conviction of the offense alleged in this Information, INDIVIOR SOLUTIONS shall forfeit to the United States property that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of knowingly and

*Attachment 3 (Exhibit B) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc*

Information

willfully making false statements relating to health care matters in violation of 18 U.S.C. § 1035, pursuant to 18 U.S.C. § 982(a)(7).

2. The property to be forfeited to the United States is a forfeiture money judgment of up to \$289,000,000 (Two Hundred Eighty-Nine Million Dollars) pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c), in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with a third person;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be subdivided without difficulty.

it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above-described forfeitable property, pursuant to 21 U.S.C. § 853(p).

Dated:

\_\_\_\_\_  
Daniel P. Bubar  
First Assistant United States Attorney  
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

\_\_\_\_\_  
Gustav W. Eyler  
Director  
Consumer Protection Branch  
United States Department of Justice

*Exhibit B to Plea Agreement  
United States v. Indivior Solutions, Inc.*

Authorized Corporate Officer's Initials: 



*Attachment 3 (Exhibit B) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc*

Information

willfully making false statements relating to health care matters in violation of 18 U.S.C. § 1035, pursuant to 18 U.S.C. § 982(a)(7).

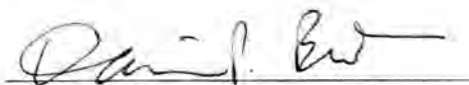
2. The property to be forfeited to the United States is a forfeiture money judgment of up to \$289,000,000 (Two Hundred Eighty-Nine Million Dollars) pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c), in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:


- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with a third person;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be subdivided without difficulty.

it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above-described forfeitable property, pursuant to 21 U.S.C. § 853(p).

Dated:



Daniel P. Bubar  
First Assistant United States Attorney  
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515



Gustav W. Eyler  
Director  
Consumer Protection Branch  
United States Department of Justice

*Exhibit B to Plea Agreement  
United States v. Indivior Solutions, Inc.*

*Authorized Corporate Officer's Initials: \_\_\_\_\_*

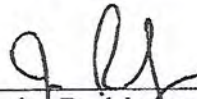
*Attachment 3 (Exhibit B) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc*

Information

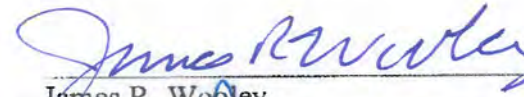
**Seen and Agreed to:**

**Indivior Solutions, Inc.**

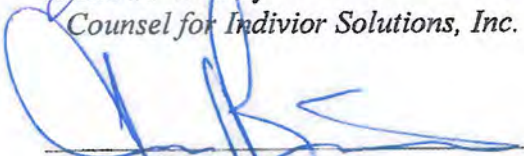
BY:

  
\_\_\_\_\_  
Javier Rodriguez  
Authorized Corporate Representative  
for Indivior Solutions, Inc.

\_\_\_\_\_  
7/24/20  
DATE

  
\_\_\_\_\_  
James R. Wooley  
Counsel for Indivior Solutions, Inc.

\_\_\_\_\_  
7/24/20  
DATE

  
\_\_\_\_\_  
Thomas W. Beimers  
Counsel for Indivior Solutions, Inc.

\_\_\_\_\_  
7/24/20  
DATE



*Attachment 3 (Exhibit C) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc*

Order of Forfeiture

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF VIRGINIA  
ABINGDON**

**UNITED STATES OF AMERICA** )  
 ) **Case No.**  
**v.** )  
 )  
**INDIVIOR SOLUTIONS, INC.** )  
 )  
**Defendant** )

**AGREED MONEY JUDGMENT ORDER OF FORFEITURE**

**IT IS HEREBY ORDERED THAT:**

**A.** Based upon the evidence of record and pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the Court finds a money judgment in the amount of \$ \_\_\_\_\_ shall be entered against defendants in that such sum represents in aggregate the amount of the proceeds of the offense of conviction, whether obtained directly or indirectly as a result of said violations or is traceable to such property. Proceeds of said offenses are subject to forfeiture pursuant to 18 U.S.C. § 981(a)(7) and 28 U.S.C. § 2461(c).

**B.** No notice is required to the extent that this Order consists solely of a money judgment against the defendant. Rule 32.2(c)(1).

**C.** Pursuant to Fed. R. Crim. P. 32.2(b)(3), the United States is authorized to conduct discovery in accordance with the Federal Rules of Civil Procedure to the extent necessary to identify and locate property subject to forfeiture as substitute assets to satisfy the money judgment.

**D.** The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

**E.** Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

**F.** The Clerk of this Court shall certify copies of this Order to counsel of record.

Attachment 3 (Exhibit C) to Resolution Agreement  
United States v. Indivior Inc. and Indivior plc

Order of Forfeiture

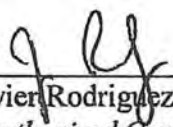
ENTERED THIS \_\_\_\_\_ DAY OF \_\_\_\_\_, 2020.

UNITED STATES DISTRICT JUDGE

Seen and Agreed to:


**Indivior Solutions, Inc.**

BY: \_\_\_\_\_

  
Javier Rodriguez  
Authorized Corporate Representative  
for Indivior Solutions, Inc.

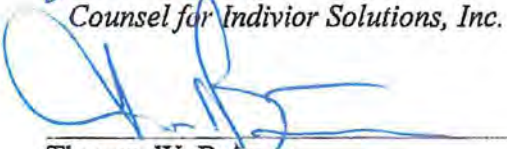
DATE

7/24/20

  
James R. Wooley  
Counsel for Indivior Solutions, Inc.

DATE

7/24/20


  
Thomas W. Beimers  
Counsel for Indivior Solutions, Inc.

DATE

7/24/20

**The United States Attorney's Office for the Western District of Virginia:**

BY: \_\_\_\_\_

  
Randy Ramseyer  
Assistant United States Attorney

DATE

July 24, 2020

*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF VIRGINIA  
ABINGDON**

**UNITED STATES OF AMERICA**

**v.**

**INDIVIOR INC. (a/k/a Reckitt  
Benckiser Pharmaceuticals Inc.) and  
INDIVIOR PLC,  
Defendants**

**Case No. 1:19cr00016**

**RESOLUTION AGREEMENT**

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and the United States Department of Justice's Consumer Protection Branch ("CPB") and Indivior Inc., and Indivior plc (Indivior Inc., Indivior plc, and all subsidiaries of either company are collectively referred to as "INDIVIOR"), pursuant to authority granted by their Board of Directors, enter into this Agreement to resolve the prosecution of INDIVIOR related to the marketing, sale, promotion and distribution of Suboxone Film in the United States.

2. This Agreement resolves all of INDIVIOR's potential federal criminal liability (except as to potential criminal tax violations, as to which the Government makes no agreement) based on the subject matter of the investigation and facts known by the USAO-WDVA and CPB and the allegations in the superseding indictment in *United States v. Indivior Inc. et al.*, Case No. 1:19CR16 (W.D. Va. August 14, 2019) ("Indictment").

3. The USAO-WDVA and CPB enter into this agreement based on the individual circumstances presented by this case, including that this resolution coupled with the July 11, 2019, resolution with INDIVIOR's former parent, Reckitt Benckiser Group, will result in a total financial recovery of \$2,000,000,000 (two billion dollars), and INDIVIOR's additional commitments to:

- a. Comply fully with the terms of the Civil Settlement Agreement (attached as Attachment 1);
- b. Comply fully with the terms of the Federal Trade Commission's ("FTC") Stipulated Order For Permanent Injunction to be entered in the United States District Court for the Western District of Virginia (attached as

*Exhibit A to Plea Agreement  
United States v. Indivior Solutions, Inc.*

*Authorized Corporate Officer's Initials:*

*JK*

*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

Attachment 2);

- c. Guarantee the performance of all financial obligations agreed to by Indivior Solutions, Inc. (Indivior Solutions), in its plea agreement (attached as Attachment 3);
- d. Comply fully with the Compliance Program set forth in Addendum A to this Agreement; and
- e. Fulfill all terms of this Agreement.

4. INDIVIOR agrees it will fulfill all of the obligations set forth in the subparagraphs of Paragraph 3 of this Agreement.

5. The Term of INDIVIOR's obligations under this Agreement will be 5 (five) years from the date all parties have signed this Agreement ("Effective Date"). However, the Term will be extended to include any time prior to INDIVIOR fully complying with all of its commitments, financial and otherwise, set forth in this Agreement.

6. INDIVIOR will pay or guarantee payment of a total of \$600,000,000 (six hundred million dollars) plus interest accrued on first payment, such that if its subsidiary, Indivior Solutions, is unable to meet its financial commitments in its plea agreement (Attachment 3 hereto), INDIVIOR guarantees those commitments will be paid. If Indivior Solutions does not make payments due on or before the dates below, INDIVIOR will honor its guarantee and will pay those amounts on or before the dates below. This total payment and/or guarantee amount shall be allocated as follows:

- a. \$300,000,000 (three hundred million dollars) plus interest at a rate of 1.25% (one and one quarter percent) per annum to be paid by INDIVIOR pursuant to the Civil Settlement Agreement (payments designated in table below as "Civil");
- b. \$10,000,000 (ten million dollars) to be paid by INDIVIOR to resolve claims by the FTC as set forth in the Stipulated Permanent Injunction (payment designated in table below as "FTC");
- c. \$245,000,000 (two hundred forty-five million dollars) [plus interest accrued on the first payment] to be paid by Indivior Solutions to be allocated between a fine, additional forfeiture, and, if the Court deems it appropriate, restitution. The Court has absolute discretion to determine how this money should be allocated between these items. If the Court deems restitution to be



*United States v. Indivior Inc. and Indivior plc***Resolution Agreement**

appropriate, pursuant to 18 U.S.C. 3663(a)(3), the parties agree the Court may order restitution in any manner it deems appropriate (payments designated in table below as "Court's Discretionary Fund");

- d. \$44,000,000 (forty-four million dollars) to be paid by Indivior Solutions for forfeiture of proceeds (payments designated in table below as "Forfeiture"); and
- e. \$1,000,000 (one million dollars) to be paid by Indivior Solutions to the Virginia Medicaid Fraud Control Unit to be used for the 25% state match of the Medicaid Fraud Control Unit grant (payment designated in table below as "VA-MFCU").

7. The payments shall be made as follows, as directed by the United States:

<b>TABLE OF PAYMENTS BY INDIVIOR SOLUTIONS AND GUARANTEED BY INDIVIOR INC. AND INDIVIOR PLC</b>				
		Designation of Payments		
Due Date	Payment Due*	Court's Discretionary Fund	Forfeiture	VA-MFCU
Put in Escrow Prior to Indivior Solutions Pleading Guilty#	\$ 54,000,000	\$ 31,000,000	\$ 22,000,000	\$ 1,000,000
1/15/2022	\$ 25,000,000	\$ 25,000,000		
1/15/2023	\$ 25,000,000	\$ 25,000,000		
1/15/2024	\$ 25,000,000	\$ 25,000,000		
1/15/2025	\$ 25,000,000	\$ 25,000,000		
1/15/2026	\$ 25,000,000	\$ 25,000,000		
1/15/2027	\$ 25,000,000	\$ 25,000,000		
12/15/2027	\$ 86,000,000	\$ 64,000,000	\$ 22,000,000	
<b>TOTAL</b>	<b>\$ 290,000,000</b>	<b>\$ 245,000,000</b>	<b>\$ 44,000,000</b>	<b>\$ 1,000,000</b>

United States v. Indivior Inc. and Indivior plc

Resolution Agreement

TABLE OF PAYMENTS BY INDIVIOR INC. AND INDIVIOR PLC			
		Designation of Payments	
Due Date	Payment Due*	Civil*	FTC
Put in Escrow Prior to Indivior Solutions Pleading Guilty#	\$ 46,000,000	\$ 36,000,000	\$ 10,000,000
1/15/2022	\$ 25,000,000	\$ 25,000,000	
1/15/2023	\$ 25,000,000	\$ 25,000,000	
1/15/2024	\$ 25,000,000	\$ 25,000,000	
1/15/2025	\$ 25,000,000	\$ 25,000,000	
1/15/2026	\$ 25,000,000	\$ 25,000,000	
1/15/2027	\$ 25,000,000	\$ 25,000,000	
12/15/2027	\$ 114,000,000	\$ 114,000,000	
<b>TOTAL</b>	<b>\$ 310,000,000</b>	<b>\$ 300,000,000</b>	<b>\$ 10,000,000</b>

#Payments due prior to Indivior Solutions pleading guilty will be placed in an escrow account. Within 3 (three) days of the Court imposing sentence, the escrow funds will be disbursed as set forth herein. For all of the escrowed amounts, in addition to the escrowed payments, Indivior Solutions will pay, and INDIVIOR will guarantee payment of, interest at the rate of 1.25% (one and one quarter percent) per annum calculated from April 9, 2020, to the time payment is made from the escrow account. The interest paid on the escrowed funds will not be credited toward the total amount due and will make the Court's Discretionary Fund greater than \$245,000,000 (two hundred forty-five million dollars).

\*All payment due for the Civil Settlement will include the amount listed plus interest of 1.25% (one and one-quarter percent) per annum calculated from April 9, 2020.

8. Any payments made shall be credited to the earliest payments due and pro rata between the different designated purposes. After the initial payment, any payments for forfeiture, fines, or restitution made ahead of the due date shall be reduced by an early payment discount of 3% (three percent) per annum. Any such payments made past the due date shall be increased by a late fee of 3% (three percent) per annum on the amount that is late, only. Imposition of a late fee is in addition to any other remedy the USAO-WDVA and CPB may pursue if INDIVIOR violates this agreement by (a) failing to make its civil payments when due or (b) failing to honor its agreement to guarantee the payments of Indivior Solutions when due.

9. Other than money returned from the State Settlement Accounts, if any, as set forth in agreements with the Medicaid Participating States, no money paid by INDIVIOR will be returned and INDIVIOR expressly releases any and all claims it may have to the money. INDIVIOR will not file any claim or otherwise contest the payment of money set forth in this Agreement, and it will not assist anyone in asserting a claim to the money.

*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

10. Nothing in this Agreement or any related document is an admission by the USAO-WDVA or CPB that the amounts paid by INDIVIOR are the maximum amounts that could, in the absence of this agreement, be recovered from INDIVIOR. If INDIVIOR does not comply with all of its obligations under this Agreement, the USAO-WDVA and CPB are not precluded from arguing or presenting evidence that the total amount to be paid by INDIVIOR should be higher.

11. INDIVIOR must notify the USAO as soon as reasonably practicable, in writing, of any event (including, but not limited to, sale, merger, dissolution, etc.) that would jeopardize its ability to pay any amounts under this Agreement. If an adverse event (including, but not limited to, sale, merger, dissolution, etc.) would jeopardize INDIVIOR's ability to pay any amounts under this Agreement, or if any payment would cause INDIVIOR to either (a) violate an existing debt covenant for which the holder(s) will not forbear, forgive or otherwise extend, or (b) incur a negative going concern or viability assessment by its auditors as required by any applicable domestic or foreign corporate governance code, accounting standard or related rule or regulation, INDIVIOR shall notify the USAO as soon as reasonably practicable. Should unrelated, unanticipated economic circumstances create a material risk that INDIVIOR may reasonably incur any of the events identified herein, INDIVIOR may request that the USAO-WDVA and CPB agree to delay any payment identified in the Table of Payments in paragraph 7 of the Resolution Agreement. The USAO-WDVA and CPB may consider such request.

12. INDIVIOR represents and warrants that it has reviewed its financial situation, it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and it reasonably believes it shall remain solvent following payment of the financial obligations set forth in this Agreement. Further, the parties warrant that, in evaluating whether to execute this Agreement, they have (a) intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to INDIVIOR, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to, and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which INDIVIOR was or became indebted to on or after the Agreement Date, within the meaning of 11 U.S.C. § 548(a)(1). INDIVIOR agrees its obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and INDIVIOR shall not argue or otherwise take the position in any such case, action, or proceeding that (1) INDIVIOR's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (2) INDIVIOR was insolvent at the time this Agreement was entered into; or (3) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to INDIVIOR. INDIVIOR acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

*Exhibit A to Plan Agreement*  
*United States v. Indivior Solutions, Inc.*

Authorized Corporate Officer's Initials: 

*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

INDIVIOR agrees all amounts payable under this agreement are not dischargeable in bankruptcy and shall be considered debt for a fine, penalty, or forfeiture payable to and for the benefit of a governmental unit pursuant to 11 U.S.C. § 523(a)(7). INDIVIOR will not contest that all forfeiture amounts ordered by the Court against Indivior Solutions represent criminal proceeds subject to forfeiture, and as such, the Government's interest in those proceeds arose on the date Indivior Solutions received those proceeds pursuant to 21 U.S.C. 853(c).

13. Within 5 (five) days of filing of the publicly filed documents that are related to the below listed documents, INDIVIOR shall provide for the exclusive use of the United States the following financial reports to the USAO and CPB (to the extent any below listed document is not related to a publicly filed quarterly document, INDIVIOR shall provide the reports by the 15<sup>th</sup> day of the month following the conclusion of the quarter):

- a. quarterly operating reports which report net disbursements and net receipts, bank account balances, and statement of operations and balance sheet for the preceding month, for Indivior plc, Indivior Finance (2014) LLC, Indivior Finance SARL, Indivior Global Holdings Ltd (a/k/a RBP Global Holdings Limited); Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.), Indivior PLC, Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.), and Indivior US Holdings Inc. (f/k/a RBP US Holdings Inc.) and any successor in interest; and
- b. a quarterly cash flow forecast that shows anticipated consolidated cash receipts and disbursements for the next quarter on a consolidated basis.

14. INDIVIOR's United States Suboxone sales force will be disbanded prior to execution of this Agreement and INDIVIOR will not reinstate a United States Suboxone sales force.

15. Neither INDIVIOR nor any affiliated U.S. entity (including, but not limited to, joint ventures) will make any false or misleading statements in the promotion of any pharmaceutical product during the term of this Agreement.

16. INDIVIOR will fully cooperate with all investigations and prosecutions, if any, by the Department of Justice related, in any way, to Suboxone or any other drug marketed or promoted by INDIVIOR. INDIVIOR's cooperation in the investigation and prosecution of individuals and entities pursuant to this paragraph includes, but is not limited to, using best efforts promptly to secure the attendance and testimony of any current or former officer, director, agent, or employee of INDIVIOR at any meeting or interview or before the grand jury or at any trial or other court proceeding; and truthfully disclosing all factual information, documents, records, or other tangible evidence not protected by a

*QR*



*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

valid claim of privilege or work product. INDIVIOR's cooperation is subject to applicable laws and regulations, including relevant data privacy and national security laws and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine. INDIVIOR expressly understands, to the extent there is conduct disclosed by INDIVIOR that does not relate to Suboxone or Subutex, such conduct will not be exempt from prosecution and is not within the scope of the non-prosecution terms of this Agreement.

17. INDIVIOR will execute and transmit all documents needed to effectuate the terms of this Agreement.

18. INDIVIOR stipulates (a) the facts and allegations set forth in the Information to which Indivior Solutions is pleading guilty are true and correct, (b) the United States had probable cause to bring all the counts in the Indictment and Superseding Indictment ("Indictment Counts") which are being dismissed under this agreement, (c) the Indictment Counts were not frivolous, vexatious or in bad faith, and (d) INDIVIOR is not, in any way, a "prevailing party" with regard to the Indictment Counts. INDIVIOR waives any claim for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

19. INDIVIOR will not, through its present or future directors, officers, employees, or agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Agreement or its attachments. If INDIVIOR makes a public statement that in whole or in part contradicts any such statement or provision, INDIVIOR may avoid being in violation of this Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by INDIVIOR's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) INDIVIOR's websites. Notwithstanding the above, INDIVIOR may avail itself of any legal or factual arguments available in defending litigation brought by a party other than the United States. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

20. The conduct for which INDIVIOR was investigated and that led to the Indictment relates solely to INDIVIOR's products Subutex, Suboxone Tablet, and Suboxone Film and not to its products launched in 2018 and thereafter.

21. Except as may otherwise be agreed by the parties in connection with a particular transaction, INDIVIOR agrees if, during the term of this Agreement, it

*United States v. Indivior Inc. and Indivior plc*Resolution Agreement

undertakes any material change in corporate form, including if it sells, merges, or transfers any portion of its business operations material to INDIVIOR's consolidated operations as they existed as of April 9, 2020, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement unless the USAO-WDVA and CPB otherwise agree in writing. INDIVIOR shall provide notice to the USAO-WDVA and CPB at least 30 (thirty) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict INDIVIOR from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the USAO-WDVA and CPB.

22. If INDIVIOR is in compliance with all of the terms of this Agreement and the Court enters a judgment and conviction order against Indivior Solutions, upon the Court entering an order requiring INDIVIOR to fully comply with this Agreement the United States will move for dismissal of the Indictment and will not prosecute or seek forfeiture against INDIVIOR or its present or former affiliates, divisions, or subsidiaries or their successors, or assigns for any criminal conduct occurring prior to the date this agreement is signed and covered by (a) the Indictment or any violations of law that were the subject matter of the Indictment, (b) the investigation by the USAO-WDVA and CPB, and/or (c) the facts currently known to the USAO-WDVA and CPB regarding the sale, promotion, or marketing of Suboxone or Subutex products in the United States.

23. Notwithstanding any other provision of this Agreement, if the USAO-WDVA or CPB, in their sole discretion, determine INDIVIOR (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement; (b) committed a felony during the term of this Agreement; or (c) knowingly and intentionally violated any provision of this Agreement, (1) the USAO-WDVA and CPB will not be bound to their agreement not to prosecute INDIVIOR for the matters covered in the Indictment, (2) INDIVIOR will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of INDIVIOR prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible, and (3) the United States may file any charges which were filed or could have been filed against INDIVIOR relating to the Indictment. It is understood any prosecution not time-barred by the applicable statute of limitations on the Effective Date of this Agreement, including time protected as the result of existing agreements

*United States v. Indivior Inc. and Indivior plc*Resolution Agreement

to toll the applicable statute of limitations, may be commenced against INDIVIOR in the event of its knowing or intentional violation of a provision of this Agreement. Accordingly, INDIVIOR has executed and agrees to be bound by the tolling agreement included as Attachment 4 to this Agreement. Should the USAO-WDVA or CPB determine that INDIVIOR has violated any provision of this Agreement, the USAO-WDVA or CPB shall provide prompt written notice to INDIVIOR addressed to its Chief Legal Officer, and to its outside counsel, James R. Wooley, Jones Day, North Point 901 Lakeside Avenue, Cleveland, Ohio 44114-1190 or to any successor INDIVIOR may designate, of the alleged violation and provide INDIVIOR with a 45 (forty-five) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA or CPB to demonstrate that no violation occurred, that any violation was unintentional or inadvertent, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by INDIVIOR.

24. INDIVIOR will agree to the entry of an order of the Court (attached as Attachment 5), as a condition of the Court's dismissal of the pending Indictment, in which INDIVIOR is ordered to comply with the terms of this Agreement and be subject to, in addition to the other remedies available in this Agreement, the jurisdiction of the Court whether for a proceeding that could result in contempt or any other remedy the Court deems appropriate should it fail to comply with any term of the Agreement. For the purposes of a dispute over an alleged violation of the Agreement, a determination by the USAO-WDVA or CPB that INDIVIOR failed to comply with a term of the agreement shall not be binding on the Court. INDIVIOR agrees nothing will divest the Court of jurisdiction, including, but not limited to, any proceeding relating to bankruptcy, insolvency, reorganization, or relief of debtors.

25. INDIVIOR shall comply with (a) the FDCA and implementing regulations governing the manufacture, marketing, sale, promotion, and distribution of Indivior products in the United States, and (b) Title 18, United States Code, Section 1347.

26. This Agreement binds the Department of Justice. Notwithstanding the foregoing, it does not bind the Tax Division of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities.

27. Indivior waives all rights, whether asserted directly or by a representative, to request or receive from the United States Department of Justice, United States Food and Drug Administration – Office of Criminal Investigations, United States Department of Health and Human Services – Office of Inspector General, United States Postal Service – Office of Inspector General, and Virginia

*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

Office of the Attorney General Medicaid Fraud Control Unit any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, the Privacy Act of 1974, 5 U.S.C. § 552a, or the Virginia Freedom of Information Act, Va. Code § 2.2-3700- 3714.

28. Nothing in this Agreement resolves, in any way, any liability of any individual.

29. If the Court rejects either the Plea Agreement of Indivior Solutions or Civil Settlement with INDIVIOR, either party may withdraw from this agreement by giving written notice to the other party within 10 (ten) days of the Court's rejection.

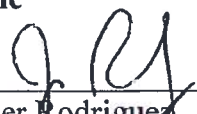
30. This Agreement, its Addendum A and Attachments 1, 2, 4, and 5, set forth all the terms of the agreement between INDIVIOR on the one hand, and the USAO-WDVA and CPB on the other. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA and CPB, an attorney for INDIVIOR, and a duly authorized representative of INDIVIOR.

31. INDIVIOR acknowledges its acceptance of this Agreement by the signature of its counsel and Officer(s). A copy of a resolution by INDIVIOR's Boards of Directors authorizing the Officer(s) to execute this Agreement and all other documents to resolve this matter on behalf of INDIVIOR is attached as Addendum B.

**Agreed to:**

**Indivior Inc.  
Indivior plc**

BY:

  
\_\_\_\_\_  
Javier Rodriguez  
Authorized Corporate Representative  
for Indivior Inc. and Indivior plc

DATE

7/24/20

Counsel has fully explained to the Boards of Directors of INDIVIOR the facts and circumstances of the prosecution and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. INDIVIOR understands the terms and conditions of this Agreement, and INDIVIOR's decision to enter into this Agreement is knowing and voluntary. INDIVIOR's execution of and entry into this Agreement is done with Counsel's consent.

*Exhibit A to Plea Agreement  
United States v. Indivior Solutions, Inc.*

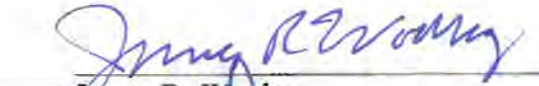
*Authorized Corporate Officer's Initials:*





*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

  
James R. Wooley  
*Counsel for Indivior Inc. and Indivior plc*

7/24/20  
DATE

  
Thomas W. Beimers  
*Counsel for Indivior Inc. and Indivior plc*

7/24/20  
DATE

**The United States Attorney's Office for the Western District of Virginia:**

BY:

DANIEL P. BUBAR  
*Attorney for the United States,  
Acting Under Authority Conferred by 28 U.S.C. Section 515*

DATE

ALBERT P. MAYER  
*Trial Attorney, Department of Justice, Civil Division,  
Commercial Litigation Branch*

RANDY RAMSEYER  
*Assistant United States Attorney*

KRISTIN L. GRAY

JOSEPH S. HALL

JANINE M. MYATT

*Special Assistant United States Attorneys / Assistant Attorneys General,  
Medicaid Fraud Control Unit, Virginia Office of the Attorney General*

GARTH W. HUSTON

*Special Assistant United States Attorney / Attorney, Federal Trade Commission*

CAROL L. WALLACK

*Trial Attorney, Department of Justice, Civil Division,  
Commercial Litigation Branch*

**The United States Department of Justice, Consumer Protection Branch:**

BY:

GUSTAV W. EYLER  
*Director*

DATE

JILL P. FURMAN  
*Deputy Director*

CHARLES J. BIRO

MATTHEW J. LASH  
*Trial Attorneys*

*United States v. Indivior Inc. and Indivior plc*

Resolution Agreement

\_\_\_\_\_  
James R. Wooley  
*Counsel for Indivior Inc. and Indivior plc*

\_\_\_\_\_  
DATE

\_\_\_\_\_  
Thomas W. Beimers  
*Counsel for Indivior Inc. and Indivior plc*

\_\_\_\_\_  
DATE

**The United States Attorney's Office for the Western District of Virginia:**

BY: \_\_\_\_\_

DANIEL P. BUBAR

*Attorney for the United States,*

*Acting Under Authority Conferred by 28 U.S.C. Section 515*

ALBERT P. MAYER

*Trial Attorney, Department of Justice, Civil Division,*

*Commercial Litigation Branch*

RANDY RAMSEYER

*Assistant United States Attorney*

KRISTIN L. GRAY

JOSEPH S. HALL

JANINE M. MYATT

*Special Assistant United States Attorneys / Assistant Attorneys General,*

*Medicaid Fraud Control Unit, Virginia Office of the Attorney General*

GARTH W. HUSTON

*Special Assistant United States Attorney / Attorney, Federal Trade Commission*

CAROL L. WALLACK

*Trial Attorney, Department of Justice, Civil Division,*

*Commercial Litigation Branch*

**The United States Department of Justice, Consumer Protection Branch:**

BY: \_\_\_\_\_

GUSTAV W. EYLER

*Director*

JILL P. FURMAN

*Deputy Director*

CHARLES J. BIRO

MATTHEW J. LASH

*Trial Attorneys*

\_\_\_\_\_  
DATE